

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings of claims in the application:

Claim 1 (Currently amended): A method of treating heart failure ~~and/or renal failure~~ in a patient, comprising delivering to said patient CGRP in an amount effective to provide symptomatic relief, ~~prevent exacerbation of symptoms, and/or prevent and/or~~ or delay progression of the disease state of heart failure in said patient, wherein said CGRP is delivered to said patient as a controlled release composition,

wherein said controlled release composition comprises a flowable thermoplastic polymer composition comprising a biocompatible polymer, a biocompatible solvent and CGRP and said composition is delivered to a bodily tissue or fluid in said patient, wherein the amounts of the polymer and the solvent are effective to form a biodegradable polymer matrix containing CGRP in situ when said composition contacts said bodily fluid tissue or fluid,

wherein said CGRP is released from said polymer matrix at a rate that will maintain circulating plasma levels of CGRP between 11 ± 5 pg/ml and 186 ± 127 pg/ml over a period of 7 to 180 days.

Claim 2 (Cancelled).

Claim 3 (Withdrawn): The method of claim 1, wherein said CGRP is in the form of a conjugate comprising CGRP coupled to a polymer.

Claim 4 (Withdrawn): The method of claim 3, wherein said polymer is a poly(alkylene glycol) or a polysaccharide.

Claim 5 (Currently Amended): The method of claim [[2]] 1, wherein the composition further comprises a controlled release additive.

Claim 6 (Cancelled).

Claim 7 (Currently amended): The method of claim [[6]] 1, wherein said composition comprises between about 0.56 and 290 mg CGRP and between about 0.01 and 5.8 mL of said composition is administered to said patient

Claim 8 (Currently amended): The method of claim [[6]] 1, wherein said composition comprises about 0.56 and 290 mg CGRP and between about 0.004 and 1.93 mL of said composition is administered to said patient.

Claim 9 (Currently Amended): The method of claim [[2]] 1, wherein said biocompatible polymer is selected from the group consisting of polylactides, polyglycolides, polyanhydrides, polyorthoesters, polycaprolactones, polyamides, polyurethanes, polyesteramides, polydioxanones, polyacetals, polyketals, polycarbonates, polyorthocarbonates, polyphosphazenes, polyhydroxybutyrates, polyhydroxyvalerates, polyalkylene oxalates, polyacrylates, polyalkylene succinates, poly(malic acid), poly(amino acids) and copolymers, terpolymers, cellulose diacetate, ethylene vinyl alcohol, and copolymers and combinations thereof.

Claim 10 (Currently amended): The method of claim [[2]] 1, wherein the polymer matrix releases CGRP by diffusion, erosion, or a combination of diffusion or erosion as the polymer matrix biodegrades in said patient.

Claim 11 (Currently amended): The method of claim [[2]] 1, wherein said CGRP is delivered via a puncture needle or catheter.

Claim 12 (Currently amended): The method of claim [[2]] 1, further comprising administering one or more drugs selected from the group consisting of anti-proliferative agents, anti-clotting agents, vasodilators, diuretics, beta-blockers, calcium ion channel blockers, blood thinners, cardiotonics, ACE inhibitors, anti-inflammatories, and antioxidants.

Claim 13 (Original): The method of claim 12, wherein said drug is added to said polymer composition prior to administration such that said solid polymer matrix further contains said drug.

Claim 14 (Original): The method of claim 12, wherein said drug is administered as a separate formulation before, simultaneously, or subsequently to administration of said polymer composition.

Claim 15 (Canceled).

Claim 16 (Original): The method of claim 1, wherein the length of said treatment is sufficient to relieve or attenuate one or more symptoms of heart failure.

Claim 17 (Withdrawn): The method of claim 1, wherein said treatment is sufficient to improve renal blood flow, glomerular filtration rates, and/or serum levels of urea and creatinine in said patient.

Claim 18 (Original): The method of claim 1, wherein said treatment is sufficient to improve the quality of life of said patient.

Claim 19 (Original): The method of claim 1, wherein said patient is a pediatric patient.

Claim 20 (Withdrawn): The method of claim 1, wherein said controlled release composition comprises biodegradable microspheres incorporating CGRP.

Claim 21 (Withdrawn): The method of claim 20, wherein said microspheres comprise poly(lactic-co-glycolic acid), poly(lactic acid), poly(caprolactone), polycarbonates, polyamides, polyanhydrides, polyamino acids, polyortho esters, polyacetals, polycyanoacrylates degradable polyurethanes, polyacrylates, ethylene-vinyl acetate copolymers, acyl substituted cellulose acetates, and derivatives and copolymers thereof.

Claim 22 (Withdrawn): The method of claim 20, wherein said CGRP is in the form of a conjugate comprising CGRP coupled to a polymer.

Claim 23 (Withdrawn): The method of claim 20, wherein said microspheres are embedded in a gel matrix.

Claim 24 (Withdrawn): The method of claim 1, wherein said controlled release composition comprises CGRP encapsulated in a liposome.

Claim 25 (Withdrawn): The method of claim 23, wherein said CGRP is in the form of a conjugate comprising CGRP coupled to a polymer.

Claim 26 (Withdrawn): The method of claim 23, wherein said polymer is a poly(alkylene glycol) or a polysaccharide.

Claim 27 (Withdrawn): The method of claim 1, wherein said controlled release composition comprises CGRP conjugated to a polymer.

Claim 28 (Withdrawn): The method of claim 1, wherein said controlled release composition is in film form.

Claim 29 (Withdrawn): The method of claim 28, wherein said film comprises polylactic acid, polyglycolic acid and mixtures and copolymers thereof.

Claim 30 (Currently amended): A method of treating heart failure ~~and/or renal failure~~ in a patient, comprising administering a flowable composition comprising a biocompatible polymer, a biocompatible solvent and CGRP to a bodily tissue or fluid in said patient, wherein the amounts of the polymer and the solvent are effective to form said polymer matrix comprising CGRP in situ when the formulation contacts said bodily fluid tissue or fluid wherein polymer matrix comprises between about 5% and 15% CGRP by weight and said CGRP is released from said polymer matrix at a rate between about 0.0008 and 0.016 $\mu\text{g}/\text{min}/\text{kg}$ body weight over a period of 7 to 180 days.

Claim 31 (Currently amended): ~~[[A]] The method of treating heart failure and/or renal failure in a patient~~ claim 1, comprising:

(a) ~~administering~~ administering CGRP to said patient by a method selected from parenteral, oral, sublingual, intranasal, intracoronary, intra-arterial, intravenous, transmucosal, or intradermal delivery for a time and at a dose effective to provide symptomatic relief, ~~prevent~~

~~exacerbation of symptoms, and/or prevent and/or or delay progression of the disease state of heart failure in said patient; and~~

~~(b) — delivering CGRP to said patient as a controlled release formulation in an amount effective to provide symptomatic relief, prevent exacerbation of symptoms, and/or prevent and/or delay progression of the disease state of heart failure in said patient.~~

Claim 32 (Canceled).

Claim 33 (Withdrawn): The method of claim 31, wherein said controlled release formulation comprises biodegradable microspheres incorporating CGRP.

Claim 34 (Withdrawn): The method of claim 31, wherein said controlled release formulation comprises wherein said controlled release composition comprises g CGRP encapsulated in a liposome.

Claim 35 (Withdrawn): The method of claim 31, wherein said controlled release formulation comprises CGRP coupled to a polymer.

Claim 36 (Withdrawn): The method of claim 31, wherein said controlled release formulation is in film form.

Claim 37 (Withdrawn): A method of preventing or reducing the risk of occurrence of myocardial infarction, comprising delivering to a human at risk of having a myocardial infarction a controlled release formulation of CGRP comprising an amount of CGRP effective to prevent or reduce the risk or occurrence of myocardial infarction.

Claim 38 (Withdrawn): The method of claim 37, wherein said controlled release formulation comprises a flowable formulation comprising a biocompatible polymer, a biocompatible solvent and CGRP wherein said formulation is delivered to a bodily tissue or fluid in said patient and a solid polymer matrix containing said CGRP is formed in situ in said tissue or fluid.

Claim 39 (Withdrawn): The method of claim 37, wherein said controlled release formulation comprises biodegradable microspheres incorporating CGRP.

Claim 40 (Withdrawn): The method of claim 37, wherein said controlled release formulation comprises wherein said controlled release composition comprises g CGRP encapsulated in a liposome.

Claim 41 (Withdrawn): The method of claim 37, wherein said controlled release formulation comprises CGRP coupled to a polymer.

Claim 42 (Withdrawn): The method of claim 37, wherein said controlled release formulation is in film form.

Claim 43 (Withdrawn): A kit comprising a first container comprising a controlled release formulation of CGRP, said formulation comprising an amount of CGRP effective to treat or prevent heart failure and/or renal failure.

Claim 44 (Withdrawn): The kit of claim 43, further comprising one or more drugs selected from the group consisting of anti-proliferative agents, anti-clotting agents, vasodilators, diuretics, beta-blockers, calcium ion channel blockers, blood thinners, cardiotonics, ACE inhibitors, anti-inflammatories, and antioxidants.

Claim 45 (Withdrawn): The kit of claim 29, further comprising a second container comprising one or more drugs selected from the group consisting of anti-proliferative agents, anti-clotting agents, vasodilators, diuretics, beta-blockers, calcium ion channel blockers, blood thinners, cardiotonics, ACE inhibitors, anti-inflammatories, and antioxidants.

Claim 46 (Withdrawn): The kit of claim 29, further comprising a puncture needle or catheter.

Claim 47 (Withdrawn): A method of counteracting ischemia due to myocardial infarction in a patient, comprising delivering to said patient an amount of CGRP effective to provide cardioprotection, reduction in infarction size, reduction in reperfusion injury, symptomatic relief,

and/or prevent exacerbation of symptoms, wherein said CGRP is delivered to said patient as a controlled release composition.